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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,171	06/06/2001	Jan F.A. Smits	CU-2481 RJS	6517

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EXAMINER

MATHEW, FENN C

ART UNIT PAPER NUMBER

3764

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,171	Applicant(s) SMITS, JAN F.A.	
	Examiner Fenn C Mathew	Art Unit 3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-10 is/are rejected.
- 7) ☒ Claim(s) 4-5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1 and 6, 8-9/1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson in view of DeRidder (U.S. 5,730,154). Patterson discloses in figures 1-12, a brace comprising a flexible frame, sized and configured to be located substantially under the toes and at a first end providing a first point on the medial side of the first phalanx of the big toe (in fig. 6, the right side of loop a), at a location between the big toe and the second toe providing a second point on the lateral side of the distal end of the big toe (left side of loop a), and at a second end providing a third point on the ball of the foot (lower strap). Furthermore, the device is capable of providing some degree of force at each of the above-mentioned points. Patterson discloses that the device can be made from flexible resilient material, but does not specify steel wire or pads. DeRidder teaches in col. 3, lines 11-14 that it is known in the orthopedic art to select from different resilient and flexible materials including steel or plastic, in order to provide stiff yet resilient materials. Thus one having ordinary skill in the art would have known to make the Patterson device from various materials including substituting steel for the flexible material of the Patterson device in order to produce a stiff yet resilient device.
3. Referring to claims 2-3, Patterson discloses proximal padding, pressing on the first phalanx of the big toe, distal padding pressing on the distal end of the big toe and

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the first phalanx and lever arm (region on bottom and left of a) pressing on the ball of the foot. If the elected structure of Patterson above is not viewed as separate structure, it would have been obvious to one having ordinary skill in the art at time the invention was made to make each of separate structure, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

4. Referring to claims 8-9, Patterson discloses a strap provided for fitting around the third toe and made from suitable fabrics. Suitable fabric include synthetics which are plastic polymers.

5. Referring to claim 10, as broadly interpreted, the distal padding carries a strap to be located around the big toe.

6. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson and further in view of Beeman and Nakamura. See the above discussion regarding Patterson. Patterson does not disclose the lever arm is provided with silicone coating or tubing. Beeman teaches in col. 3, lines 3-6 and 20-27 that it is known to coat body supports made with plastic or other suitable material to allow for prolonged contact with the skin without irritation. As such one skilled in the art would have known to coat or provide the lever arm with a tubing made of rubber or other suitable material in order to provide prolonged contact without skin irritation. Nakamura teaches in col. 2, lines 59-63 that silicone is an optimal material to have close to the skin for a prolonged period of time without skin irritation. Thus, one having ordinary skill in the art would have been motivated to use silicone as the tubing over the lever arm of the Patterson device in

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order to use an optimal material to prevent skin irritation during prolonged periods of use.

Allowable Subject Matter

7. Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record fails to teach a hallux valgus brace as defined in the base limitations and further comprising an adjustable arm on which the distal pad is disposed.

Response to Arguments

8. Applicant's arguments filed 06/17/2004 have been fully considered but they are not persuasive. As best understood by the Examiner, Patterson is capable of providing force at the points as defined by the Applicant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn C Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

fcm

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October 18, 2004

JR

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

10/18/04